

LEADER FLU AND SEVERE COLD AND COUGH- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride powder, for solution

Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Cardinal Health Flu & Severe Cold & Cough Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- in a child under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed (see overdose warning)
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information

- each packet contains: potassium 5 mg and sodium 43 mg
- phenylketonurics: contains phenylalanine 17 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, FD&C blue #1, FD&C red #40, flavor, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Daytime Flu & Severe Cold & Cough

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Pain Reliever/Fever Reducer

Cough Suppressant

Nasal Decongestant

Berry Infused with Menthol Flavor

Relieves:

Nasal Congestion,

Cough, Body Ache,

Sore Throat Pain,

Headache, Fever

COMPARE TO THERAFLU® DAYTIME SEVERE COLD & COUGH active ingredients

100% Money Back Guarantee

6 PACKETS

LEADERTM

LEADERTM

NDC 70000-0287-1

Daytime

Flu & Severe Cold & Cough

Acetaminophen
Dextromethorphan HBr
Phenylephrine HCl

Pain Reliever / Fever Reducer
Cough Suppressant
Nasal Decongestant



Berry Infused
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COMPARE TO
THERAFLU®
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active Ingredients*


100% Money
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PARENTS:

Learn about teen medicine abuse

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100% Money Back Guarantee

Return to place of purchase if not satisfied.



CONVENIENT RESEALING TAB

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

Drug Facts

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Phenylephrine HCl 10 mg.....	Nasal decongestant

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Drug Facts (continued)

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Questions or comments?

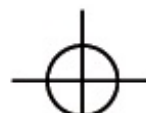
1-800-719-9260

Gluten Free

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OPEN OTHER END

CIN 5326590 REV. 4/17





LEADER FLU AND SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0287
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics			
Color	WHITE (mixture of white to light to dark red particles) , RED	Score	
Shape		Size	
Flavor	BERRY, MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0287-1	6 in 1 CARTON; Type 0: Not a Combination Product	04/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/12/2017	

Labeler - Cardinal Health (097537435)

Revised: 8/2019

Cardinal Health